

EPA Reg. Jacket 71185-5 Vol. 1



43/A-2-3 Jacket
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 18, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-358393
EPA File Symbol or Registration Number: 80990-2
Product Name: AGROSCIENCE OXYTETRACYCLINE TECHNICAL
FUNGICIDE/BACTERICIDE AGRICULTURAL TERRAMYCIN
EPA Application Receipt Date: 28-Jun-2005
EPA Waiver Request Receipt date: 28-Jun-2005
EPA Company Number: 80990
Company Name: AGROSOURCE, INC.

TAW W. RICHARDSON
AGROSOURCE, INC.
PO Box 1341
MOUNTAINSIDE, NJ 07092-0341

SUBJECT: Approval of 100% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has approved your request for 100% waiver of the pesticide registration fee associated with the action referenced above. The decision review period for this action begins on the date of this letter.

The Action has been identified as Action Code: R34

NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL
STATEMENTS; SOURCE CHANGES TO AN UNREGISTERED SOURCE);

If you have any questions, please contact Pesticide Registration Service Fee
Ombudsman, at (703) 305-6249.

Sincerely,

for Arnold E. Layne, Director
Information Technology & Resources Management Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

John F. Wright
AgroSource, Inc.
P.O. Box 1341
Mountainside, NJ 07092-0341

OCT 14 2005

Subject: AgroSource Oxytetracycline Technical Fungicide/
Bactericide Agricultural Oxytetracycline
EPA Reg. No. 80990-2
Your Submission Dated: June 22, 2005

Dear Mr. Wright:

The revised basic Confidential Statement of Formula (CSF) dated 6/22/05 referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act as amended is acceptable. Please note that this CSF supercedes all previous CSFs for this product and will be added to the regulatory file.

The alternate CSFs (dated 6/22/05) was also found to be acceptable and will be added to the regulatory file. The product chemistry review dated October 6, 2005 is included for your records.

If you have any questions, please contact Lana Coppolino by phone at 703-305-0086 or via email at coppolino.lana@epa.gov.

Sincerely,

A handwritten signature in cursive script, reading "Mary L. Waller", is positioned above the typed name.

Mary L. Waller
Product Manager (21)
Fungicide Branch
Registration Division (7505C)

Enclosure

FEE

DATE OUT: 06/OCT/2005

FEE: PRODUCT CHEMISTRY REVIEW OF: A TECHNICAL GRADE TGAI [X]
DP BARCODE #:D319449 EPA RECEIVED DATE: 21/AUG/2005 REG NO.:80990-2
PRODUCT NAME: Agrosience Oxytetracycline Technical Fungicide/Bactericide A
COMPANY NAME : Agrosource, Inc. MRID :465839-01 ACTION CODE: R34
PPC NUMBER OF THIS TGAI 006308 FOOD USE [X] DECISION NO.: 358393

FROM: Sami Malak, Chemist *S. Malak*
Technical Review Branch/RD (7505C)

SBm 1076105

TO: 21 Mary Waller/Lana Coppolino
Fungicide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 24/JUN/2005, Product & Regulatory Associates, L. L. C., an agent for the applicant requested amended registration of subject product to allow an alternate manufacturing site to be claimed in an alternate CSF dated 22/JUN/2005. A basic CSF dated 22/JUN/2005 was also included to approve product's transfer from Reg. No. 74896-5 to Reg. No. 80990-2.

FINDINGS:

1a. The subject product was previously reviewed by this reviewer under the name RG OTC Technical, manufactured by [REDACTED]
[REDACTED] This TGAI was subsequently registered by RegGuide under Reg.No. 74896-5 (DP #289846, S. Malak, 09/SEP/2003). The product was then transferred to the applicant under Reg. No 80990-2.

1b. The submitted basic CSF by the applicant dated 22/JUN/2005, product name: AgroSource Oxytetracycline Technical Fungicide/Bactericide Agricultural Oxytetracycline, manufactured by [REDACTED]
[REDACTED] is identical in composition to the current basic CSF by RegGuide, Reg. No. 74896-5. This reviewer has no objections for its approval to effect the transfer from RegGuide to Agrosource, Inc.

1c. The submitted alternate CSF by the applicant dated 22/JUN/2005, product name: AgroSource Oxytetracycline Technical Fungicide/Bactericide Agricultural Oxytetracycline, manufactured by [REDACTED]
[REDACTED] is substantially similar in composition to the submitted basic CSF, also dated 22/JUN/2005.

2. The submitted information in MRID #465839-01 support approval of the submitted alternate CSF (Finding 1c above).

Product ingredient source information may be entitled to confidential treatment

3. The nominal concentration of subject product is 98.3% plus 0.92% related compounds as cited in the submitted CSFs by the applicant, as well as RegGuide CSF and their label approved on 26/Mar/2004.

4a. The submitted basic CSF by the applicant dated 22/JUN/2005 must supersede the current basic CSF dated 16/JAN/2003 by RegGuide.

4b. The applicant should be advised to submit a new label under Reg. No. 80990-2 to supersede the current label by RegGuide, Reg. No. 74896-5.

CONCLUSIONS:

TRB has no objections for approval of the new manufacturing site for subject product to be claimed in the submitted alternate CSF dated 22/JUN/2005 (Finding 1c above).

NOTE TO RM:

Please note Findings 4a & 4b above.

REVIEW OF PRODUCT CHEMISTRY DATA (MRID #460585-01:

1. A statement of data confidentiality dated 22/JUN2005 was included with this submission claiming confidentiality of any of the submitted data on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of this data was moved to Confidential Appendix A.
2. A GLP statement dated 22/JUN/2005 was included with this submission to the effect that the submitter was neither the sponsor of the study nor conducted it and does not know whether it has been conducted in accordance with the GLP requirements of 40CFR§160.

830-1800 Enforcement Analytical Method:

Adequate analytical method for the TGAI is available for enforcement. The method was previously submitted and reviewed in connection with registration of oxytetracycline, Reg. Nos. 69678-2 & 74896-5.

A published analytical method was included with a previous submission, MRID #458430-02, entitled "Oxytetracycline Hydrochloride, European Pharmacopoeia 4, pages 9-11."



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 30, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-358393
EPA File Symbol or Registration Number: 80990-2
Product Name: AGROSCIENCE OXYTETRACYCLINE TECHNICAL
FUNGICIDE/BACTERICIDE AGRICULTURAL TERRAMYCIN
EPA Receipt Date: 28-Jun-2005
EPA Company Number: 80990
Company Name: AGROSOURCE, INC.

TAW W. RICHARDSON
AGROSOURCE, INC.
PO Box 1341
MOUNTAINSIDE, NJ 07092-0341

SUBJECT: Receipt of Amendment and 100% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application for amendment and 100% small business waiver request. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

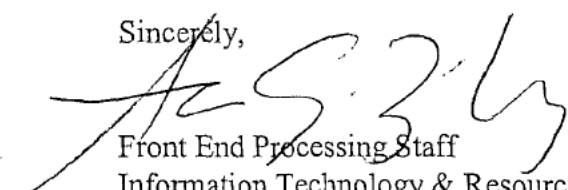
The Action has been identified as Action Code: R34

NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL
STATEMENTS;SOURCE CHANGES TO AN UNREGISTERED SOURCE);

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If the determination indicates that payment is due, you will receive instructions for submitting payment at that time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 305-6249.

Sincerely,


Front End Processing Staff

Information Technology & Resources Management Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 1, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

AGROSOURCE, INC.
PO Box 1341
MOUNTAINSIDE, NJ 07092-0341

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 28-JUN-05. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Product & Regulatory Associates, L.L.C.

June 24, 2005

Ms. Mary L. Waller (PM 21)
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency, CM-2
Room 266A, Crystal Mall 2
1801 S. Bell Street
Arlington, VA 22202

Subject: AgroSource Oxytetracycline Technical Fungicide/Bactericide Agriculture
Oxytetracycline,
EPA Reg. No. 80990-2
Application for Pesticide Amendment for Alternate Technical Sources
PRIA Category: R34 Non-Fast Track Source Change to Unregistered Sources
w/Complete Fee Waiver Request

Dear Ms. Waller:

As the authorized representative for AgroSource, Inc., EPA Company No. 80990, I am submitting an application for pesticide amendment for AgroSource Oxytetracycline Technical Fungicide/Bactericide EPA Reg. No. 80990-2. The objective is to amend the existing technical registration to include additional manufacturing sources.

This registration submission falls into PRIA Category: R34 non-fast track, source change to unregistered sources. A complete fee waiver request is also submitted with this application.

The registration application request contains the following enclosed materials:

Volume 1 of 2

Administrative Documents

- Transmittal
- Cover letter
- Registration Application (EPA Form 8570-1)
- Confidential Statement of Formula (CSF) (EPA Form 8570-4)
- Certification of CSF
- Supporting documentation for fee waiver request (brown envelop)

4201 Church Road, Suite 334 Mount Laurel, NJ 08054-2231
Telephone 856 424-1528

Page 2 of 2

“AgroSource Oxytetracycline Technical Fungicide/Bactericide Agricultural Oxytetracycline, Product Chemistry, Group A: Product Identity, Composition and Analytical Test Guidelines” 05-ASI-103, June 22, 2005 (3 copies)

Sincerely,

John F. Wright
Product & Regulatory Associates, LLC
Authorized Representative of AgroSource, Inc.

A collection of 15 small, stylized line drawings of various insects, including beetles, flies, and bees, arranged in a grid-like pattern.

Product & Regulatory Associates, L.L.C.

Transmittal

Date: June 24, 2005

Subject: AgroSource Oxytetracycline Technical Fungicide/Bactericide
Agricultural Oxytetracycline
Application for Pesticide Amendment for Alternate Technical Sources
EPA Reg. No. 80990-2

PRIA R34 Non-Fast Track Source Change to Unregistered Sources
Category: w/Complete Fee Waiver Request

Submitter: AgroSource, Inc
P. O. Box 1341
Mountainside, NJ 07092-0341

c/o Product & Regulatory Associates, LLC
4201 Church Road
Suite 334
Mount Laurel, NJ 08054

The registration application request contains the following enclosed materials:

Volume 1 of 2

Administrative Documents

- Transmittal
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- Registration Application (EPA Form 8570-1)
- Confidential Statement of Formula (CSF) (EPA Form 8570-4)
- Certification of CSF
- Supporting documentation for fee waiver request (brown envelop)

Volume 2 of 2

"AgroSource Oxytetracycline Technical Fungicide/Bactericide Agricultural Oxytetracycline, Product Chemistry, Group A: Product Identity, Composition and Analytical Test Guidelines" 05-ASI-103, June 22, 2005 (3 copies)

Signature: _____

John F. Wright Authorized Representative for AgroSource, Inc.

Product & Regulatory Associates, LLC
e-mail: JwrightCH@comcast.net

Telephone: 856.424.1528

4201 Church Road, Suite 334 Mount Laurel, NJ 08054-2231
Telephone 856 424-1528



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number AgroSource, Inc. 80990-2	2. EPA Product Manager Mary Waller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) AgroSource Oxytetracycline Technical Fungicide/Bactericide	PM# 21	
5. Name and Address of Applicant (Include ZIP Code) AgroSource, Inc. c/o Product & Regulatory Associates, LLC 4201 Church Road, Suite 334 Mount Laurel, NJ 08054 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application for Pesticide Amendment for Alternate Technical Sources for EPA Reg. No. 80990-2
PRIA Category: R34 Non-Fast Track Source Change to Unregistered Sources w/Complete Fee Waiver Request

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

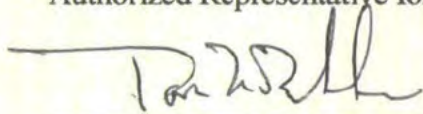
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name John F. Wright	Title Authorized Representative for AgroSource	Telephone No. (Include Area Code) 856.424.1528	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Authorized Representative for AgroSource, Inc.		
4. Typed Name John F. Wright	5. Date 6/22/05		

CERTIFICATION STATEMENT

CONFIDENTIAL STATEMENT OF FORMULA

I hereby certify for purposes of FIFRA § 12(a)(1)(c), the description of the composition of **AgroSource Oxytetracycline Technical Fungicide/Bactericide Agricultural Oxytetracycline, EPA Reg. No. 80990-2** refers to the composition set forth on the Statement of Formula and supporting materials. This description includes the representations that (1) no ingredient will be present in the product in an amount greater than the upper certified limit or in an amount less than the lower certified limit (if required) specified for that ingredient in a currently approved Statement of Formula (or calculated by the Agency); and (2) if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the statement of Formulas.

Authorized Representative for AgroSource, Inc.



Taw W. Richardson
President

06/27/05
Date

13

JUN 27 2005

Mr. John F. Wright
Representative for AGROSOURCE, INC.
Product & Regulatory Associates, LLC
4201 Church Road Suite 334
Mount Laurel, NJ 08054

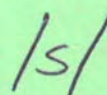
Dear Mr. Wright:

This is in response to your request dated May 25, 2005 to change the primary brand name for **EPA Registration 80990-2** from AgroSource Oxytetracycline Technical Fungicide/Bactericide to:

**AGROSOURCE OXYTETRACYCLINE TECHNICAL
FUNGICIDE/BACTERICIDE
AGRICULTURAL OXYTETRACYCLINE**

Your request for the name change is **accepted** and the change will be made to the Agency's records. All future correspondence on this product should reference the new name.

Sincerely yours,



Sherada D. Hobgood
Notifications Review Coordinator
Registration Division (7505C)

P D & R Associates

Product Development & Regulatory Associates

May 25, 2005

Ms. Sherada Hobgood
Document Processing DESK (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall-2
1801 South Bell Street
Arlington, VA 22202-5401

Subject: AgroSource Oxytetracycline Technical Fungicide/Bactericide
Agricultural Terramycin
EPA Reg. No. 80990-2
Change in Primary Brand Name via Notifications per PR Notice 98-10

Dear Ms. Hobgood:

As the authorized representative for AgroSource, it has chosen to revise the subject labeling via the notification process. This notification is consistent with PR 98-10.

The **green** highlighted changes include:

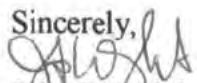
- Modify brand name, Section II A.

The AgroSource Oxytetracycline Technical Fungicide/Bactericide Agricultural Oxytetracycline brand name should become the primary brand name on file for this product. This will replace the name listed above.

To complete this notification application, enclosed please find:

- Application for Pesticide: Notification(EPA Form 8750-1)
- AgroSource Oxytetracycline Technical Fungicide/Bactericide Agricultural Terramycin revised labeling with changes highlighted (1 copy)
- A self addressed stamped post card

I trust that this information will assist the Agency in its efforts to complete this notification. If you have any question in regard to this mater, feel free to contact me at (856) 424-1528 or JWrightCH@comcast.net.

Sincerely,

John F. Wright
Product & Regulatory Associates, LLC
Authorized Representative of AgroSource, Inc

cc: Taw Richardson, AgroSource, Inc.

4201 Church Road, Suite 334 Mount Laurel, NJ 08054-2231
Telephone 856 424-1528





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number AgroSource, Inc. 80990-2	2. EPA Product Manager Mary Waller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) AgroSource Oxytetracycline Technical Fungicide/Bactericide	PM# 21	
5. Name and Address of Applicant (Include ZIP Code) AgroSource, Inc. c/o Product & Regulatory Associates, LLC 4201 Church Road, Suite 334 Mount Laurel, NJ 08054 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. NOTIFICATION Product Name JUN 27 2005	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of PRIMARY brand name change per PR Notice 98-10.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name John F. Wright		Title Authorized Representative for AgroSource		Telephone No. (Include Area Code) 856.424.1528	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Authorized Representative for AgroSource, Inc.			
4. Typed Name John F. Wright		5. Date 5/25/05			

**AgroSource Oxytetracycline
Technical
Fungicide/Bactericide
Agricultural Oxytetracycline**

NOTIFICATION
JUN 27 2005

This material is a non-sterile, non-pharmaceutical grade, technical antibiotic product intended for formulation into EPA-registered end-use pesticide products.

Not for Resale Under This Label

Active Ingredient:

Oxytetracycline Hydrochloride*98.30%
Related Compounds.....0.92%
Other Ingredients:0.78%
100.00%

* minimum 83.5% oxytetracycline

EPA Reg. No. 80990-2

EPA Est. No. 80990-CHN-001

**KEEP OUT OF THE REACH OF CHILDREN
DANGER**

FIRST AID

Call a poison control center or doctor immediately for treatment advice.

If In Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If On Skin or Clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact InfoTrac at 1-800-535-5053 for emergency medical treatment information.

See Side Panel for Additional Precautions

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product.

AgroSource, Inc.
P. O. Box 1341
Mountainside, NJ 07092-0341

NET CONTENTS: 25 KG

**PRECAUTIONARY STATEMENTS
Hazards To Humans & Domestic Animals**

DANGER: Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). May cause allergic skin reactions. Do not breathe dust. Wear dust mask and rubber gloves. Wash thoroughly with soap and water after handling and before eating drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. This material is not to be used for medical, veterinary or human purposes.

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

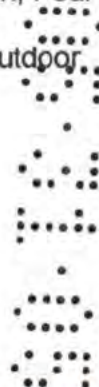
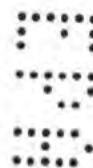
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This manufacturing use product is intended to be formulated as an active ingredient into end-use pesticide products. The manufacturer of such products shall be responsible for registering its product with EPA as a pesticide for acceptable use patterns.

Only for formulation into an anti-bacterial pesticide for the following uses:

Terrestrial Foods – Nectarine, Peach, Pear

Terrestrial Non-Food & Domestic Outdoor



5/25/05

Storage & Disposal

Do not contaminate water, food or feed by storage or disposal.

Storage: Keep container tightly closed and sealed. Product is moisture, temperature and light sensitive. Product is hygroscopic so protect from moisture. Store in a cool (<77°F, 25°C), dry place away from heat and open flames with minimum exposure to the atmosphere. Avoid extremes in temperature.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into process equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If the drum cannot be reused, dispose of in the same manner.

Conditions of Sale and Limitation of Warranty and Liability

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials, resistant strains or other influencing factors in the use of the product, which are beyond the control of AgroSource, Inc. or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold AgroSource, Inc. and Seller harmless for any claims relating to such factors.

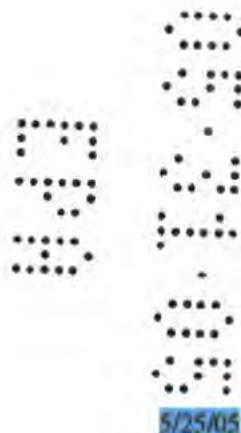
AgroSource, Inc. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or AgroSource, Inc., and Buyer and User assume the risk of any such use. AGROSOURCE, INC. MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A

PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall AgroSource, Inc. or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF AGROSOURCE, INC. AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF AGROSOURCE, INC. OR SELLER, THE REPLACEMENT OF THE PRODUCT.

AgroSource, Inc. and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of AgroSource, Inc.

Made in China



FEB 15 2005

Mr. John F. Wright
Representative for AGROSOURCE, INC.
Product Development & Regulatory Associates, LLC
4201 Church Road Suite 334
Mount Laurel, NJ 08054-2231

Dear Mr. Wright:

This is in response to your request dated January 13, 2005 to change the primary brand name for **EPA Registration 80990-2** from RG OTC Technical to:

**AGROSOURCE OXYTETRACYCLINE TECHNICAL
FUNGICIDE/BACTERICIDE AGRICULTURAL TERRAMYCIN**

Your request for the name change is **accepted** and the change will be made to the Agency's records. All future correspondence on this product should reference the new name.

Sincerely yours,

/s/

Sherada D. Hobgood
Notifications Review Coordinator
Registration Division (7505C)



United States
Environmental Protection Agency
Washington, DC 20460

☐
☐
☒

Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number AgroSource, Inc. 80990-2	2. EPA Product Manager Mary Waller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) AgroSource Oxytetracycline Technical Fungicide/Bactericide	PM# 21	
5. Name and Address of Applicant (Include ZIP Code) AgroSource, Inc. c/o Product & Regulatory Associates, LLC 4201 Church Road, Suite 334 Mount Laurel, NJ 08054 <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: NOTIFICATION EPA Reg. No. _____ Product Name FEB 15 2005	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of PRIMARY brand name, pesticide category and change in warranty statement as in cover letter per PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name John F. Wright		Title Authorized Representative for AgroSource		Telephone No. (Include Area Code) 856.424.1528	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Authorized Representative for AgroSource, Inc.			
4. Typed Name John F. Wright		5. Date 1/13/05			

AgroSource, Inc.
P. O. Box 1341
Mountainside, New Jersey 07016

Telephone (908) 931-9001

taw.richardson@agrosource.net

October 13, 2004

Document Processing Desk
Fungicide Branch
Registration Division
Office of Pesticide Programs (7504C)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attention: Mary Waller
Product Manager 21

Subject: John F. Wright- AgroSource Agent

Dear Ms. Waller:

Please be informed that AgroSource, Inc. authorizes John F. Wright to act as an agent for our interactions with EPA.

If you need additional information or have any questions feel free to contact me.

Sincerely,



Taw W. Richardson, President

cc: John F. Wright



FEB 15 2005

**AgroSource Oxytetracycline
Technical
Fungicide/Bactericide
Agricultural Terramycin**

This material is a non-sterile, non-pharmaceutical grade, technical antibiotic product intended for formulation into EPA-registered end-use pesticide products.

Not for Resale Under This Label

Active Ingredient:

Oxytetracycline Hydrochloride*98.30%

Related Compounds.....0.92%

Other Ingredients:0.78%

100.00%

* minimum 83.5% oxytetracycline

EPA Reg. No. 80990-2

EPA Est. No. 80990-CHN-001

**KEEP OUT OF THE REACH OF CHILDREN
DANGER**

FIRST AID

Call a poison control center or doctor immediately for treatment advice.

If In Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If On Skin or Clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact InfoTrac at 1-800-535-5053 for emergency medical treatment information.

See Side Panel for Additional Precautions

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product.

AgroSource, Inc.
P. O. Box 1341
Mountainside, NJ 07092-0341

NET CONTENTS: 25 KG

**PRECAUTIONARY STATEMENTS
Hazards To Humans & Domestic Animals**

DANGER: Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). May cause allergic skin reactions. Do not breathe dust. Wear dust mask and rubber gloves. Wash thoroughly with soap and water after handling and before eating drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. This material is not to be used for medical, veterinary or human purposes.

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This manufacturing use product is intended to be formulated as an active ingredient into end-use pesticide products. The manufacturer of such products shall be responsible for registering its product with EPA as a pesticide for acceptable use patterns.

Only for formulation into an anti-bacterial pesticide for the following uses:

Terrestrial Foods – Nectarine, Peach, Pear

Terrestrial Non-Food & Domestic Outdoor



Storage & Disposal

Do not contaminate water, food or feed by storage or disposal.

Storage: Keep container tightly closed and sealed. Product is moisture, temperature and light sensitive. Product is hygroscopic so protect from moisture. Store in a cool (<77°F, 25°C), dry place away from heat and open flames with minimum exposure to the atmosphere. Avoid extremes in temperature.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into process equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If the drum cannot be reused, dispose of in the same manner.

Conditions of Sale and Limitation of Warranty and Liability

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials, resistant strains or other influencing factors in the use of the product, which are beyond the control of AgroSource, Inc. or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold AgroSource, Inc. and Seller harmless for any claims relating to such factors.

AgroSource, Inc. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or AgroSource, Inc., and Buyer and User assume the risk of any such use. AGROSOURCE, INC. MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A

PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall AgroSource, Inc. or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF AGROSOURCE, INC. AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF AGROSOURCE, INC. OR SELLER, THE REPLACEMENT OF THE PRODUCT.

AgroSource, Inc. and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of AgroSource, Inc.

Made in China



P D & R Associates

Product Development & Regulatory Associates

January 13, 2005

Ms. Sherada Hobgood
Document Processing DESK (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall-2
1801 South Bell Street
Arlington, VA 22202-5401

Subject: RG OTC Technical
EPA Reg. No. 80990-2

Notifications per PR Notice 98-10

Dear Ms. Hobgood:

As the authorized representative for AgroSource, it has chosen to revise the subject labeling via the notification process. This notification is consistent with PR 98-10.

The **green** highlighted changes include:

- Modify brand name properly to protect its ownership, Section II A.
- Added the Pesticide Category, Section II.K.1.
- Change in the warranty statement in the box on the first page to remove redundant language, Section II I & J.

The AgroSource Oxytetracycline Technical Fungicide/Bactericide Agricultural Terramycin brand name should become the primary brand name on file for this product. This will replace the name listed above.

Besides the changes outlined above, other non notification **blue** highlighted changes are:

- Added the latest EPA Est. No. 80990-CHN-001, Section IV.C.
- Added net contents: 25 Kg, Section IV.B.
- Added copyright ownership and date, Section IV.C.
- Added "Made in China", Section IV.F.5
- Corrected typographical error in Storage & Disposal, Section IV.A.



4201 Church Road, Suite 334 Mount Laurel, NJ 08054-2231
Telephone 856 424-1528

January 13, 2005

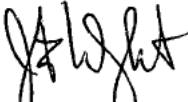
Page 2 of 2

To complete this notification application, enclosed please find:

- Application for Pesticide: Notification(EPA Form 8750-1)
- Authorized Agent's letter
- AgroSource Oxytetracycline Technical Fungicide/Bactericide Agricultural Terramycin revised labeling with changes highlighted (1 copy)
- A self addressed stamped post card

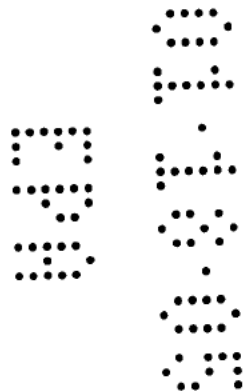
I trust that this information will assist the Agency in its efforts to complete this notification. If you have any question in regard to this mater, feel free to contact me at (856) 424-1528 or JWrightCH@comcast.net.

Sincerely,



John F. Wright
Product & Regulatory Associates, LLC
Authorized Representative of AgroSource, Inc

cc: Taw Richardson, AgroSource, Inc.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 13, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

TAW W. RICHARDSON
AGROSOURCE, INC.
PO BOX 1341
MOUNTAINSIDE, NJ 07092-0341

Gentlemen:

Subject: Transfer of Pesticide Registrations and Data From Company Number 74896 to
Company Number 80990

Pursuant to your request in your letter and transfer agreement of July 12, 2004, we have approved the transfer of the following registrations and data from REGGUIDE, company number 74896 to AGROSOURCE, INC., company number 80990.

The effective date of these changes is the date of this letter.

<u>Registered Products</u>	<u>Old EPA Reg. No.</u>	<u>New EPA Reg. No.</u>
RG OTC 17 WP	74896-4	80990-1
RG OTC TECHNICAL	74896-5	80990-2 ✓

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into

supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

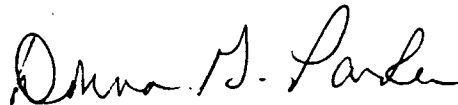
Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer dated July 12, 2004 to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date AGROSOURCE, INC. will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact me at (703) 305-6474.

Sincerely,



Donna G. Parker
Information Management Specialist
Information Services Branch
Information Resources & Services Div. (7504C)

cc: MS. SHARON M. JOHNSTON, ESQ.
REGGUIDE
509 TOWER VALLEY DRIVE
HILLSBORO, MO 63050



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg.
Number:
74896-5

Date of Issuance:
MAR 26 2004

NOTICE OF PESTICIDE:
☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:
Conditional

Name of Pesticide Product:
RG OTC Technical

Name and Address of Registrant (include ZIP Code):

RegGuide
509 Tower Valley Drive
Hillsboro, MO 63050

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(C) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Make the following label change:

Revise the EPA Registration Number to read, "EPA Reg. No. 74896-5".
3. The data for UV/visible absorption (MRID 461813-01) fulfills the requirement that this information be submitted.

Signature of Approving Official:

Mary L. Waller, Product Manager (21)

Date:

MAR 26 2004

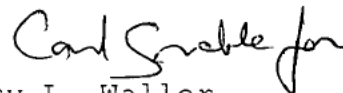
page 2
EPA Reg. No. 74896-5

Submit one copy of the final printed label before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely yours,



Mary L. Waller
Product Manager (21)
Fungicide Branch
Registration Division (7505C)

Enclosure

7505C:CGrable:cg:3/23/04

RG OTC Technical

This material is a non-sterile, non-pharmaceutical grade, technical antibiotic product intended for formulation into EPA-registered end-use pesticide products.

Not for Resale Under This Label

Active Ingredient:

Oxytetracycline Hydrochloride*98.30%

Related Compounds.....0.92%

Other Ingredients:0.78%

100.00%

*minimum 83.5% oxytetracycline

EPA Reg. No. 74896-

EPA Est. No.

**KEEP OUT OF THE REACH OF CHILDREN
DANGER**

FIRST AID

Call a poison control center or doctor immediately for treatment advice.

If In Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If On Skin or Clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact InfoTrac at 1-800-535-5053 for emergency medical treatment information.

See Side Panel for Additional Precautions

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened and undamaged, and the purchase price will be refunded.

RegGuide

509 Tower Valley Drive
Hillsboro, MO 63050

NET CONTENTS:

PRECAUTIONARY STATEMENTS

Hazards To Humans & Domestic Animals

DANGER: Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). May cause allergic skin reactions. Do not breathe dust. Wear dust mask and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. This material is not to be used for medical, veterinary, or human purposes.

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This manufacturing use product is intended to be formulated as an active ingredient into end-use pesticide products. The manufacturer of such products shall be responsible for registering its product with EPA as a pesticide for acceptable use patterns.

Only for formulation into an anti-bacterial pesticide for the following uses:

Terrestrial Food – Nectarine, Peach, Pear

Terrestrial Non-Food & Domestic Outdoor

ACCEPTED
with COMMENTS
In EPA Letter Dated

MAR 26 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
74896-5

Storage & Disposal

Do not contaminate water, food or feed by storage or disposal.

Storage: Keep container tightly closed and sealed. Product is moisture, temperature and light sensitive. Product is hygroscopic so protect from moisture. Store in a cool (77°F, 25°C), dry place away from heat and open flames with minimum exposure to the atmosphere. Avoid extremes in temperature.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into process equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If the drum cannot be reused, dispose of in the same manner.

Conditions of Sale and Limitation of Warranty and Liability

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials, resistant strains or other influencing factors in the use of the product, which are beyond the control of RegGuide or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold RegGuide and Seller harmless for any claims relating to such factors.

RegGuide warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or RegGuide, and Buyer and User assume the risk of any such use. REGGUIDE MAKES NO WARRANTIES OF MERCHANTABILITY OR OF

FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall RegGuide or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF REGGUIDE AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF REGGUIDE OR SELLER, THE REPLACEMENT OF THE PRODUCT.

RegGuide and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of RegGuide.

EFFICACY REVIEW

DATE: IN 2/11/04 OUT 3/22/04FILE OR REG. NO. 74896-2

PETITION OR EXP USE PERMIT NO. _____

DATE DIVISION RECEIVED 1/15/04DATE OF SUBMISSION 1/13/04

TYPE PRODUCT(S): I, D, H, (F,) N, R, _____

DATA ACCESSION NO(S) _____ RECORD NO. 5954760PRODUCT MANAGER NO. 21PRODUCT NAME(S) RG OTC TechnicalCOMPANY NAME Reg GuideSUBMISSION PURPOSE new technical

CHEMICAL AND FORMULATION oxyltetracycline hydrochloride,
98.30%, related compounds, 0.92%,
other ingredients 0.78%

CONCLUSIONS AND RECOMMENDATIONS The proposed label is
acceptable.

(Per meeting of 12/16/03, it was agreed that
acute Tox data would be bridged from existing
data but the signal word would be Danger
due to high pH.)

C. Greene, FB/RD(75055)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Carl / 5754760

February 11, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

REGGUIDE
509 TOWER VALLEY DRIVE
HILLSBORO, MO 63050

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 15-JAN-04. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

RegGuide

January 13, 2004

Document Processing Desk (APPL)
Fungicide Branch
Registration Division
Office of Pesticide Programs (7504C)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

ATTN: Mary Waller
Product Manager 21

SUBJECT: APPLICATION FOR PESTICIDE REGISTRATION
RG OTC Technical; EPA File Symbol: 74896-L
Response to Agency Letter Dated November 7, 2003

Dear Ms. Waller:

In response to your letter, enclosed please find the following materials in support of the application for registration of the above-subject product:

1. Application for Pesticide Registration
2. Revised Draft Labeling (5 copies)
3. Data Volumes 1 through 1 (3 copies)

A transmittal document is attached as page three of this letter.

1) There was some confusion regarding the petition for oxytetracycline hydrochloride active ingredient. In a meeting held December 16, 2003, Geo Logic informed EPA that oxytetracycline hydrochloride is CAS # 2058-46-0; the same compound as hydroxytetracycline monohydrochloride, which is the name used in the Reregistration Eligibility Document (RED). Thus, it was agreed between the parties that these are the same compound, that the RED supports oxytetracycline hydrochloride and that data on file related to all registered oxytetracycline-based products can be cited.

2) Chemistry requires that an Ultra-Violet Visibility Spectrum be submitted. These data are included in this submission.

3) Data related to melting point was also requested by Chemistry. This information is provided in our original submission for oxytetracycline hydrochloride active ingredient in Volume 1 of 3/61-1 Product Identity and Disclosure of Ingredients/Product identity and composition/A1.1/Page 6 of 14: *mp about 220° C* (*mp* refers to Melting Point). There is also a reference in Volume 1 of 3/61-2 (b)/Discussion of Formation of Impurities/D. Discussion of formation of impurities/Appendix A : MSDS Active Ingredient/Page 12: *Decomposes at temperature exceeding 180°*. The prior statement agrees with the description in the RED/III. Science Assessment/TGAI Hydroxytetracycline Monohydrochloride: Melting Point- Decomposes above 180° C. Thus, RegGuide believes that this requirement has been satisfied.

4) Chemistry noted that there are related substances that should be indicated on the label in conjunction with the active ingredient. However, these compounds were included in the Other Ingredients on the previous CSF and Label. Therefore, we have revised the label as follows: 98.3% Oxytetracycline Hydrochloride, 0.92% Related Compounds and 0.78% Other Ingredients.

5) During the December 16, 2003 meeting, Toxicology and Product Management indicated that they expected to waive the acute studies based on the clarification in item 1) above. However, there was some question expressed about eye irritation. We request the Agency grant this registration without a new eye irritation study at this time. We have revised the signal word to DANGER on the label to address this concern.

6) Per the review of RG OTC 17 (EPA File Symbol: 74896-U), the directions for use related to formulation into products intended for tree injection and anti-foulant paint additives have been deleted.

If you need additional information or have any questions, please do not hesitate to contact me at (636) 942-2583 or e-mail to: Johnston@RegGuide.net.

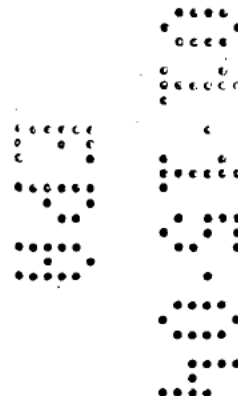
Sincerely,



Sharon M. Johnston
President

Enclosures

cc: Taw Richardson; Geo Logic



TRANSMITTAL DOCUMENT

Applicant: RegGuide
509 Tower Valley Drive
Hillsboro, MO 63050

EPA File Symbol No.: 74896-L

Product Name: RG OTC Technical

Registration Action: Application for New Product Registration

Date: January 13, 2004

Supporting Data:

<u>MRID No.</u>	<u>Volume No.</u>	<u>OPPTS Guideline Reference No.</u>	<u>Study Type</u>
46181301	1 of 1	830.7050	Product Properties: UV/Visible Absorption RG OTC Technical

MAR 26 2004

Note to the File:

A meeting was held on 12/16/2003 to discuss registration of RegGuide oxytetracycline products; EPA Reg. Nos. 74896-U and -L. Attendance list attached. The initial reviews of the products by TRB tox and chem sections had been sent to the consultant and the meeting was in response to comments in those review.

The primary discussion was whether the acute data would support the registration. The products were not substantially similar to the referenced products. It was agreed that the data could be bridged. The eye irritation could not be bridged because the pH was higher. The eye irritation study will be waived provided that the signal word is changed to reflect toxicity of solutions with similar pH.

The company will comply with comments by product chemistry. Uses in antifouling paint and for tree injection will be deleted.



Carl Grable
Fungicide Branch
Registration Division (7505C)

Meeting w/ Geo Logic on oxytetracycline 12/16/03

name	organization	phone
Carl Grable	RD/FB	(703) 305-7392
John Redden	RD/TRB	(703) 305-1969
Shyam Mathur	RD/TRB	(703) 308-9374
Taw Richardson		
Sami Malak	RD/TRB	703-308-9365
Mary Walker	RD/FB	703 308-9354



Taw Richardson
<geologic@comcast.net>

To: Carl Grable/DC/USEPA/US@EPA
cc: SJohns1825@aol.com, johnston@regguide.net
Subject: Meeting 74896-L & U

12/02/03 01:28 PM

Carl,

As discussed today by phone, I request a meeting with EPA to discuss the recent response to EPA File Symbol 74896-L and 74896-U. I believe that there may be some confusion regarding the name used for the compound. We submitted under the name oxytetracycline hydrochloride. EPA deemed this to be different from the two compounds supported by the RED; hydroxytetracycline monohydrochloride and calcium oxytetracycline. However, oxytetracycline hydrochloride is the same as hydroxytetracycline monohydrochloride. They are synonymous names for CAS Number 2058-46-0 and Chemical Number 006308.

Considering this fact relative to the comments in the letters dated November 7, 2003, we believe that data is available to satisfy most of what was noted. Thus, we would like to clarify this matter so we can receive these registrations as soon as possible. I have attached a suggested Agenda for the meeting. Please let me know if this meets with your approval.

I can be available for a meeting on the following days; December 9-12 & 15-17. If none of these work I can try to be available the latter part of this week (which is currently booked but may come available) or other days over the next couple of weeks. Please let me know what will work for you. I clearly hope to accomplish this as far ahead of the Holidays as possible.

Just to avoid any confusion, Sharon Johnston at RegGuide is the Geo Logic regulatory consultant. She submitted these petitions on behalf of Geo Logic and has sent a letter to EPA specifically authorizing Geo Logic access.

Regards,

Taw Richardson
Geo Logic Corporation
P. O. Box 1341
Mountainside, NJ 07092-0341
Telephone (908) 233-1315



Email geologic@comcast.net EPA Mtg Agenda 12-00-03.doc

**AGENDA
EPA-GEO LOGIC MEETING
DECEMBER 2003**

RG OTC Technical 74896-L

Review similarity for reference data (3a)
UV-Visibility & Melting Point/Range (4a)
Related Substances & Nominal Concentration (7b)
Label revisions

RG OTC 17 WP 74896-U

Tree Injection use (1, 5)
Signal Word (2, 3, 4)
One year Storage Stability Data & Corrosion Characteristic Data (9)

() refers to the reference numbers from the letters dated November 7, 2003.

NOV 7 2003

Ms. Sharon M. Johnston
RegGuide
509 Tower Valley Drive
Hillsboro, MO 63050

Subject: RG OTC Technical
EPA File Symbol 74896-L
Your Submission of January 16, 2003

Dear Ms. Johnston:

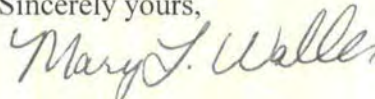
Enclosed are copies of the reviews for product chemistry and acute toxicity of this product.. The reviews indicate that the information submitted with this application is not adequate to register the product. Additional consideration will be given to this application upon receipt of the requested data.

As indicated in the toxicology review, this product is not substantially similar to the referenced product so the six basic acute toxicity tests must be submitted unless another product can be cited which is substantially similar. Additionally, it was noted that no determination of the adequacy of the toxicological data base was made. It was also noted that MRID numbers of data originally cited to support the similar product must be included.

The Reregistration Eligibility Document (RED) for Hydroxytetracycline monohydrochloride and Oxytetracycline calcium was published in March 1993. The RED clearly states that only data supporting these two forms were rereviewed and supported for reregistration. Therefore, specific data on oxytetracycline hydrochloride must be cited in addition to the acute tests.

Additional product chemistry data are also requested.. Submit data on UV/Visible Absorption and Melting Point/Melting Range (OPPTS Guidelines 830.7050 and 830.7200).

Sincerely yours,



Mary L. Waller
Product Manager (21)
Fungicide Branch
Registration Division (7505C)

Enclosures
7505C:CGrable:cg:10/20/03

EFFICACY REVIEW

DATE: IN 5/5/03 OUT 10/20/03FILE OR REG. NO. 74896-6

PETITION OR EXP USE PERMIT NO. _____

DATE DIVISION RECEIVED 1/23/03DATE OF SUBMISSION 1/16/03

TYPE PRODUCT(S): I, D, H, (F,) N, R, _____

DATA ACCESSION NO(S) _____ RECORD NO. 5628812PRODUCT MANAGER NO. 21PRODUCT NAME(S) RG BTC TechCOMPANY NAME RaguideSUBMISSION PURPOSE me-too, substantially similar?CHEMICAL AND FORMULATION oxytetracycline hydrochloride,98.3% powder.CONCLUSIONS AND RECOMMENDATIONS Not substantiallysimilar. Additional tox + chem data
required.Obj -C. Grable FB/RD(7505C)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

TECHNICAL REVIEW BRANCH
SIMILARITY CLINIC DETERMINATION

July 23, 2003

MEMORANDUM

Subject: RG OTC Technical
DP Barcode: D289847
Case No: 065335
PC Codes: 006308 Oxytetracycline hydrochloride

From: Tracy Keigwin *TK*
Technical Review Branch
Registration Division (7505C)

Byron T. R...
7-23-03

To: Carl Grable, PM 21
Fungicide Branch
Registration Division (7505C)

Applicant: RegGuide
509 Tower Valley Drive
Hillsboro, MO 63050

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Oxytetracycline Hydrochloride	98.30
<u>Inert Ingredient(s)</u>	<u>1.70</u>
Total:	100.00

ACTION REQUESTED: PM requests determination of similarity between EPA Reg. No. 100-1176 and EPA File Symbol 74896-L.

BACKGROUND: RegGuide has applied for the registration of RG OTC Technical, EPA File Symbol 74896-L and is claiming similarity to Oxytetracycline Calcium Technical, EPA Reg. No. 100-1176. The active ingredient in EPA File Symbol is 74896-L is Oxytetracycline Hydrochloride. The active ingredient in EPA Reg. No. 100-1176 is Oxytetracycline Calcium.

RECOMMENDATIONS: Although both products contain a somewhat commensurate amount of oxytetracycline (96% in EPA Reg. No. 100-1176 and "minimum 83.5% oxytetracycline" in EPA File Symbol 74896-L) the pH of EPA File Symbol 74896-L is significantly different from that of EPA Reg. No. 100-1176. This difference would certainly affect the acute toxicity profile, making it dissimilar to that of EPA Reg. No. 100-1176. This action is denied.

Note Reviewer: Please inform the registrant that if similarity to another product is being claimed the MRID numbers that were originally used to support the cited product are required.

This memorandum pertains only to the decision concerning whether the subject product is similar to the cited product(s) from an acute toxicological viewpoint. For the purposes of this action, TRB has made no determination of the adequacy of the toxicological data base or the precautionary label of the cited product(s).

DATE OUT: 09/SEP/2003

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: A TECHNICAL GRADE TGAI [X]
DPBARCODE #: D289846 EPA RECEIVED DATE: 23/JAN/2003 FILE SYMBOL/REG NO: 74896-L
PRODUCT NAME: RG OTC Technical, 98.3% Oxytetracycline Hydrochloride
COMPANY NAME: RegGuide FOOD USE [X] MRID NO: 458430-01 to -03
PPC NUMBER OF THIS TGAI: 006308 ACTION CODE: 165 CASE NO.: 065335

FROM: Sami Malak, Chemist *Sami Malak*
Technical Review Branch/RD (7505C)

512u 9/11/03

TO: 21 Mary Waller/Carl Grable
Fungicide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 16/JAN/2003 the applicant requested a FIFRA sec. 3(c)(3)(B)(i)(I) "me-too" registration of subject product claiming its similarity to Oxytetracycline Calcium Technical, Reg. No. 69678-2. In support of the application, the applicant included product chemistry data, a proposed basic CSF dated 16/JAN/2003, a proposed label EPA received 23/JAN/2003, Certificate With Respect to Citation of Data, and Data Matrix.

FINDINGS:

1. The subject product was produced by [REDACTED] of [REDACTED]. The product's purity is 98.3% in the form of Oxytetracycline Hydrochloride [4-(Dimethylamino)-1,4,4 α ,5,5 α ,6,11,12 α -octahydro-3,5,6,10,12,12 α -hexahydro-6-methyl-1-11-dioxo-2-hapthacanecarboxamide mono-hydrochloride], CAS # 2058-46-0, Reg. No. 74896-L.
2. The subject product, a fungicide, is intended for formulating other fungicide products.
- 3a. The subject product is not similar to Oxytetracycline Calcium Technical, Reg. No. 69678-2 because of differences in: (a) the nominal concentration between the pending product 98.3% oxytetracycline hydrochloride equivalent to 83.5% oxytetracycline and the registered product 50% oxytetracycline calcium, equivalent to 96% oxytetracycline; and (b) the composition since the registered product contains a large volume of inorganic salts not found in the pending product.
- 3b. Because of Finding 3(a) above, review of this application was conducted as per the regulations of FIFRA sec. 3(c)(5) or 3(c)(7).
- 4a. The applicant should be advised to submit applicable product chemistry data requirements of the following two properties in Group "B", OPPTS Test Guidelines, Series 830: GRNs 830.7050 UV/Visible Absorption, and GRN 830.7200 Melting Point/Melting Range.
- 4b. Except for the data gaps identified in Findings 4(a) above, the submitted product chemistry data is adequate and support a FIFRA sec. 3(c)(7) registration of subject product.
5. Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with registration of oxytetracycline, Reg. No. 69678-2. A published analytical method was included with this submission, MRID #458430-02, entitled "Oxytetracycline Hydrochloride, European Pharmacopoeia 4, pages 9-11." Validation data for the analytical method regarding recovery, accuracy, precision,

and linearity are adequate. Sample calculations and chromatograms were included with this submission.

- 6a. The label claim nominal concentrations of 98.3% Oxytetracycline Hydrochloride is consistent with that in the basic CSF dated 16/JAN/2003 and in compliance with the regulations of PR Notice 91-2. Further, the storage and disposal statement and the physical or chemical hazards statement are in compliance with the regulations of 40CFR§156.10.
- 6b. The label ingredient statement may need to be revised [refer to Finding 7(b)] below.
- 7a. The proposed basic CSF dated 16/JAN/2003, was filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2). All ingredients claimed on the CSF are cleared for use in pesticide formulations intended for food uses.
- 7b. If the three "Related Substances" listed in the basic CSF are pesticidally active, they must be indicated on the label as such "Related compounds at 0.92%". It follows that the label claim nominal concentration for the active ingredient must be changed to 97.3% instead of 98.3%, while no change in the percentage of "Other Ingredients" listed at 1.7%.

CONCLUSIONS:

- 1. From the product chemistry view point, the subject product is not similar in composition to Oxytetracycline Calcium Technical, Reg. No. 69678-2 [Finding 3(a)].
- 2. After resolving Findings 6(b) and 7(b) above, TRB will have no objections for approval of the submitted label EPA received on 23/JAN/2003 and basic CSF dated 16/JAN/2003.
- 3. At this time, TRB has no objections for a conditional registration as per the regulations of FIFRA sec. 3(c)(7) registration of subject product until the data gaps in Finding 4(a) and the deficiencies in Conclusion 2 above are resolved.

VIEW OF PRODUCT CHEMISTRY DATA (MRID #460585-01):

- 1. A statement of data confidentiality dated 16/JAN/2003 was included with this submission claiming confidentiality of any of the submitted data on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of this data was moved to Confidential Appendix A.
- 2. A GLP statement dated 16/JAN/2003 was included with this submission to the effect that the submitted studies were conducted in compliance with the GLP requirements of 40CFR§160.

830-1800 Enforcement Analytical Method:

Adequate analytical method for the TGAI is available for enforcement. The method was previously submitted and reviewed in connection with registration of oxytetracycline, Reg. No. 69678-2.

A published analytical method was included with this submission, MRID #458430-02, entitled

"Oxytetracycline Hydrochloride, European Pharmacopoeia 4, pages 9-11."

Validation data for the analytical method regarding recovery, accuracy, precision, and linearity are adequate. Sample calculations and chromatograms were included with this submission.

Table 1: Physical and Chemical Properties of Oxytetracycline Hydrochloride; 40CFR158.190				
GRN	Requirement	MRID	Status ¹	Result ² or Deficiency
8306302	Color	458430-03	A	Yellow.
8306303	Physical State	458430-03	A	Crystalline powder.
8306304	Odor	458430-03	A	Odorless.
8306313	Stability	458430-03	A	Stable at normal conditions. Decomposes at 180° C, and exposure to strong sunlight or to temperature exceeding 90° C in moist air causes it to darken. Its potency diminished in solutions pH below 2, and is rapidly destroyed by alkali hydroxide solution.
8306314	Oxidation/Reduction		NA	
8306315	Flammability		NA	
8306316	Explosibility		NA	
8306317	Storage Stability	458430-03	A	Stable for a period of two years.
8306319	Miscibility		NA	
8306320	Corrosion Characteristics		NA	
8307000	pH	458430-03	A	2.3 to 2.9 in 1% water solution.
8307050	UV/Visible Absorption		G	
8307100	Viscosity		NA	
8307200	Melting Point/ Melting Range		G	
8307220	Boiling Point/ Boiling Range		NA	
8307300	Density/ Relative Density/ Bulk Density	458430-03	A	5.0 lbs/ft ³
8307370	Dissociation Constant in Water	458430-03	NA	The product is water soluble salt.
830.7550/ 7560/7570	Partition Coefficient (Octanol/Water)	458430-03	NA	The product is water soluble salt.
830.7840 830.7860	Water Solubility	458430-03	NA	Freely soluble in water.
830.xxxx	Solubility in Organic Solvents	458430-03	NA	Sparingly soluble in alcohol.

Table 1: Physical and Chemical Properties of Oxytetracycline Hydrochloride; 40CFR158.190				
GRN	Requirement	MRID	Status ¹	Result ² or Deficiency
8307950	Vapor Pressure	458430-03	NA	The product is salt.
¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable; G = Data gap; U = Needs upgrading..				
² For example, "brown" for 830.6302; "155° C" for 830.7200.				

**Identity, Composition, Formulation, and Analysis, Subgroup A, Series 830.1550 to 830.1800
(40 CFR 158.155 to 158.180)**

Table: 2 Guideline Reference NO.(GRN 830.)/Title	Data Fulfilled	MRID No.
830.1550 Product identity and composition	Y	458430-01
830.1600 Description of materials used to produce the product	Y	458430-01
830.1650 Description of production process	Y	458430-01
830.1620 Description of formulation process		
830.1670 Discussion of formation of impurities	Y	458430-01
830.1700 Preliminary analysis	Y	458430-01
830.1750 Certified limits	Y	458430-01
830.1800 Enforcement analytical method	Y	458430-01
Explanations: Y =The requirements were fulfilled; N = The requirements not fulfilled; N/A = Not applicable; G = Data gap; U = Requires upgrading; I = Incomplete or in progress; W = Waived.		

GRN 830.1550 Product Identity:

Chemical Name: 4-(Dimethylamino)-1,4,4 α ,5,5 α ,6,11,12 α -octahydro-3,5,6,10,12,12 α -hexahydro-6-methyl-1-11-dioxo-2-hapthacanecarboxamide mono-hydrochloride.

Common Name: Oxytetracycline Hydrochloride

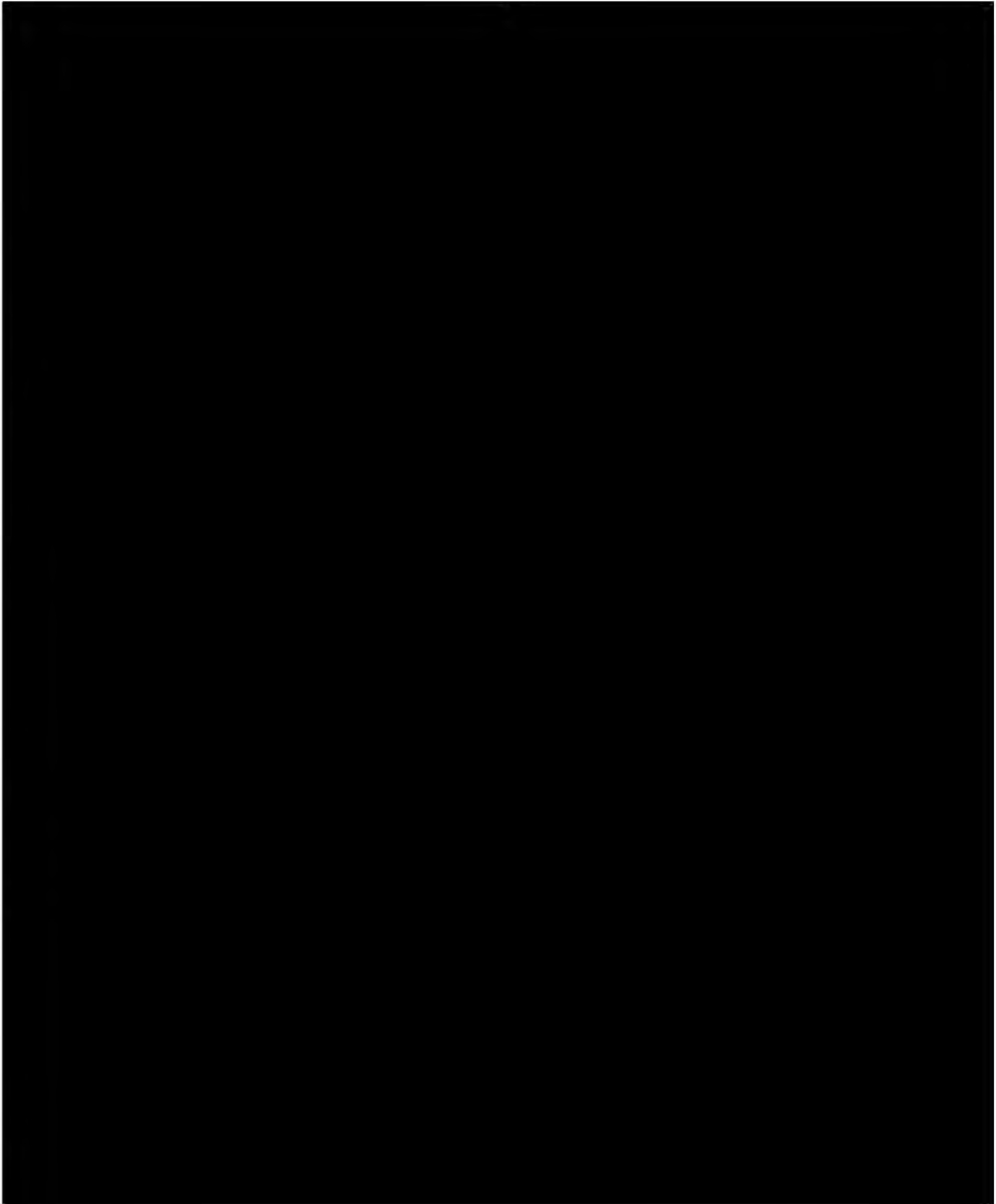
Reg. No. 74896-L.

Product Name: Technical Fungicide.

Chemical Abstract Number: 2058-46-0

Empirical Formula: C₂₂H₂₅ClN₂O₉

Molecular Weight: 496.9



GRN 830.1600 Description of Materials Used to Produce the Product

Refer to MRID #458430-01

GRN 830.1620 Description of Production Process

Detailed description of the manufacturing process are described in MRID #458430-01

GRN 830.1670 Discussion of Formation fo Impurities

Impurities reported are the same as those listed in the table above under GRN 830.1550.

830-1750 Certified Limits:

The applicant reported the same certified limits as those in product's basic CSF dated 16/JAN/2003.



United States
 Environmental Protection Agency
 Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

299973

Application for Pesticide - Section I

1. Company/Product Number 74896-L	2. EPA Product Manager Mary Waller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) RG OTC Technical	PM# 21	
5. Name and Address of Applicant (Include ZIP Code) RegGuide 509 Tower Valley Drive Hillsboro, MO 63050 <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 69678-2 Product Name Oxytetracycline Calcium Technical	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1.0 to 55 lbs		5. Location of Label Directions <input checked="" type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Sharon M. Johnston		Title President		Telephone No. (Include Area Code) (636) 942-2583	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title President			
4. Typed Name Sharon M. Johnston		5. Date 1-16-03			

458430-00

RegGuide

January 16, 2003

Document Processing Desk (APPL)
Fungicide Branch
Registration Division
Office of Pesticide Programs (7504C)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

ATTN: Mary Waller
Product Manager 21

SUBJECT: APPLICATION FOR PESTICIDE REGISTRATION
RG OTC Technical; EPA File Symbol: 74896-1

Dear Ms. Waller:

Enclosed, please find the following materials in support of the application for registration of RG OTC Technical:

1. Application for Pesticide Registration
2. Confidential Statement of Formula
3. Certification with Respect to Citation of Data
4. Data Matrix Sheets
5. Draft Labeling (5 copies)
6. Data Volumes 1 through 3 (3 copies)

A transmittal document is attached as page two of this letter.

If you need additional information or have any questions, please do not hesitate to contact me at (636) 942-2583 or e-mail to: Johnston@RegGuide.net.

Sincerely,


Sharon M. Johnston, Esq.

Enclosures

TRANSMITTAL DOCUMENT

Applicant: RegGuide
509 Tower Valley Drive
Hillsboro, MO 63050

Company No.: 74896

Product Name: RG OTC Technical

Registration Action: Application for New Product Registration

Date: January 16, 2003

Supporting Data:

<u>MRID No.</u>	<u>Volume No.</u>	<u>EPA Guideline Reference No.</u>	<u>Study Type</u>
<u>45843001</u>	1 of 3	61-1, 2(a), 2(b)	Product Identity and Composition of RG OTC Technical
<u>45843002</u>	2 of 3	62-1, 2, 3	Analysis and Certification of Product Ingredients of RG OTC Technical
<u>45843003</u>	3 of 3	63 series	Physical/Chemical Properties of RG OTC Technical Determination of Product Chemistry

RG OTC Technical

This material is a non-sterile, non-pharmaceutical grade, technical antibiotic product intended for formulation into EPA-registered end-use pesticide products.

Not for Resale Under This Label

Active Ingredient:

Oxytetracycline Hydrochloride*98.30%

Other Ingredients:1.70%
100.00%

*minimum 83.5% oxytetracycline

EPA Reg. No. 74896-

EPA Est. No.

**KEEP OUT OF THE REACH OF CHILDREN
CAUTION**

FIRST AID

Call a poison control center or doctor immediately for treatment advice.

If In Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If On Skin or Clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact InfoTrac at 1-800-535-5053 for emergency medical treatment information.

See Side Panel for Additional Precautions

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened and undamaged, and the purchase price will be refunded.

RegGuide

509 Tower Valley Drive
Hillsboro, MO 63050

NET CONTENTS:

PRECAUTIONARY STATEMENTS

Hazards To Humans & Domestic Animals

CAUTION: May cause allergic skin reactions. Do not breathe dust. Wear dust mask and rubber gloves. Wash with plenty of soap and water after handling. Remove contaminated clothing and wash clothing before reuse. This material is not to be used for medical, veterinary, or human purposes.

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This manufacturing use product is intended to be formulated as an active ingredient into end-use pesticide products. The manufacturer of such products shall be responsible for registering its product with EPA as a pesticide for acceptable use patterns.

Only for formulation into an anti-bacterial pesticide for the following uses:

Terrestrial Food – Nectarine, Peach, Pear (includes tree injection)

Terrestrial Non-Food & Domestic Outdoor (Includes tree injection)

Forestry – Tree injection

Aquatic Non-Food – Marine Anti-foulant products (including paints)

Storage & Disposal

Do not contaminate water, food or feed by storage or disposal.

Storage: Keep container tightly closed and sealed. Product is moisture, temperature and light sensitive. Product is hygroscopic so protect from moisture. Store in a cool (77°F, 25°C), dry place away from heat and open flames with minimum exposure to the atmosphere. Avoid extremes in temperature.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into process equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If the drum cannot be reused, dispose of in the same manner.

Conditions of Sale and Limitation of Warranty and Liability

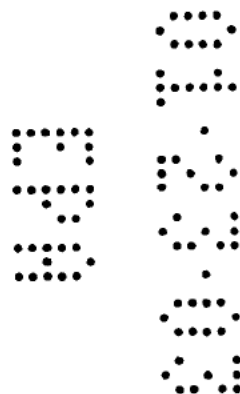
The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials, resistant strains or other influencing factors in the use of the product, which are beyond the control of RegGuide or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold RegGuide and Seller harmless for any claims relating to such factors.

RegGuide warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or RegGuide, and Buyer and User assume the risk of any such use. REGGUIDE MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR

ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall RegGuide or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF REGGUIDE AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF REGGUIDE OR SELLER, THE REPLACEMENT OF THE PRODUCT.

RegGuide and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of RegGuide.



	United States	<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
	Environmental Protection Agency		299973
	Washington, DC 20460		

Application for Pesticide - Section I

1. Company/Product Number 74896-L	2. EPA Product Manager Mary Waller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) RG OTC Technical	PM# 21	
5. Name and Address of Applicant (Include ZIP Code) RegGuide 509 Tower Valley Drive Hillsboro, MO 63050 <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 69678-2 Product Name Oxytetracycline Calcium Technical	

Section - II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.
---	---

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1.0 to 55 lbs		5. Location of Label Directions <input checked="" type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Sharon M. Johnston	Title President	Telephone No. (Include Area Code) (636) 942-2583	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title President		
4. Typed Name Sharon M. Johnston	5. Date 1-16-03		



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

299973

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. _____ No. per container _____	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. _____ No. per container _____	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name	Title	Telephone No. (Include Area Code)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature	3. Title	
4. Typed Name	5. Date	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



United States
Environmental Protection Agency
Washington, DC 20460

☐
☐
☐

Registration
Amendment
Other

OPP Identifier Number

299973

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name	Title	Telephone No. (Include Area Code)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature	3. Title	
4. Typed Name	5. Date	

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2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

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1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

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3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

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- 1-5. Self-explanatory.
6. EPA Use Only.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 24, 2003

OFFICE OF PESTICIDE
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SHARON M. JOHNSTON, ESQ.
REGGUIDE
2348 SHELBY 116
LEONARD, MO 63451

PRODUCT NAME: RG OTC TECHNICAL
COMPANY NAME: REGGUIDE
OPP IDENTIFICATION NUMBER: 299973
EPA FILE SYMBOL: 74896-L
EPA RECEIPT DATE: 01/23/03

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for a new registration and it has passed an administrative screen for completeness.

Please note that this is only a notification of receipt of your application. This is only the first step in the application process and does NOT constitute approval.

If you have any questions, please contact Registration Division, Risk Management Team 21, at (703) 308-9354.

Sincerely,

A handwritten signature in cursive script that reads "Patricia A. Moore".

Front End Processing Staff
Information Services Branch
Information Resources and Services Division

N/ET

B

RegGuide

January 16, 2003

Document Processing Desk (APPL)
Fungicide Branch
Registration Division
Office of Pesticide Programs (7504C)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

ATTN: Mary Waller
Product Manager 21

SUBJECT: APPLICATION FOR PESTICIDE REGISTRATION
RG OTC Technical; EPA File Symbol: 74896-

Dear Ms. Waller:

Enclosed, please find the following materials in support of the application for registration of RG OTC Technical:

1. Application for Pesticide Registration
2. Confidential Statement of Formula
3. Certification with Respect to Citation of Data
4. Data Matrix Sheets
5. Draft Labeling (5 copies)
6. Data Volumes 1 through 3 (3 copies)

A transmittal document is attached as page two of this letter.

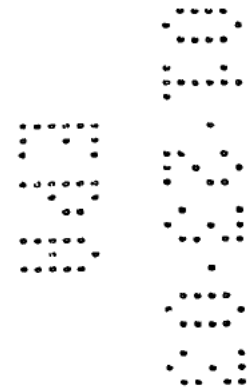
If you need additional information or have any questions, please do not hesitate to contact me at (636) 942-2583 or e-mail to: Johnston@RegGuide.net.

Sincerely,



Sharon M. Johnston, Esq.

Enclosures



Sharon M. Johnston, Esq.
509 Tower Valley Drive
Hillsboro, MO 63050

Tel: 636-942-2583
Fax: 636-948-9720
e-mail: Johnston@RegGuide.net

TRANSMITTAL DOCUMENT

Applicant: RegGuide
509 Tower Valley Drive
Hillsboro, MO 63050

Company No.: 74896

Product Name: RG OTC Technical

Registration Action: Application for New Product Registration

Date: January 16, 2003

Supporting Data:

<u>MRID No.</u>	<u>Volume No.</u>	<u>EPA Guideline Reference No.</u>	<u>Study Type</u>
_____	1 of 3	61-1, 2(a), 2(b)	Product Identity and Composition of RG OTC Technical
_____	2 of 3	62-1, 2, 3	Analysis and Certification of Product Ingredients of RG OTC Technical
_____	3 of 3	63 series	Physical/Chemical Properties of RG OTC Technical Determination of Product Chemistry

509



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number RegGuide, 509 Tower Valley Drive, Hillsboro, MO 63050 (636) 942-2583	EPA Registration Number/File Symbol 74896-5
Active Ingredient(s) and/or representative test compound(s) Oxytetracycline Hydrochloride	Date January 16, 2003
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food & Non-Food, Greenhouse Food & Non-Food, Forestry, Aquatic Non-Food	Product Name RG OTC Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

Typed or Printed Name and Title

01-16-03

Sharon M. Johnston / President

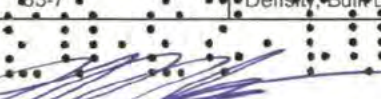


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DATA MATRIX

Date January 16, 2003			EPA Reg No./File Symbol	74896-	Page 1 of 9
Applicant's/Registrant's Name & Address		RegGuide 509 Tower Valley Drive Hillsboro, MO 63050		Product RG OTC Technical	
Ingredient		Oxytetracycline Hydrochloride			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1	Chemical Identity		RegGuide	OWN	
61-2	Beginning Materials & Manufacturing Process		RegGuide	OWN	
61-3	Discussion of Formation of Impurities		RegGuide	OWN	
62-1	Preliminary Analysis		RegGuide	OWN	
62-2	Certification of Ingredient Limits		RegGuide	OWN	
62-3	Analytical Method to Verify Certified Limits		RegGuide	OWN	
63-2	Color		RegGuide	OWN	
63-3	Physical State		RegGuide	OWN	
64-4	Odor		RegGuide	OWN	
63-6	Boiling Point				NA - Solid
63-7	Density, Bulk Density or Specific Gravity		RegGuide	OWN	
Signature 			Name and Title Sharon M. Johnston President		Date January 16, 2003

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DATA MATRIX

Date January 16, 2003		EPA Reg No./File Symbol 74896-		Page 2 of 9	
Applicant's/Registrant's Name & Address RegGuide 509 Tower Valley Drive Hillsboro, MO 63050		Product RG OTC Technical			
Ingredient Oxytetracycline Hydrochloride					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-8	Solubility		RegGuide	OWN	
63-9	Vapor Pressure		RegGuide	OWN	
63-10	Dissociation Constant		RegGuide	OWN	
63-11	Octanol/Water Partition Coefficient		RegGuide	OWN	
63-12	pH		RegGuide	OWN	
63-13	Stability		RegGuide	OWN	
63-17	Storage Stability		RegGuide	OWN	
63-20	Corrosion Characteristics		RegGuide	OWN	
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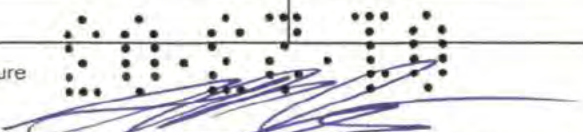


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Date January 16, 2003		EPA Reg No./File Symbol 74896-		Page 3 of 9	
Applicant's/Registrant's Name & Address RegGuide 509 Tower Valley Drive Hillsboro, MO 63050		Product RG OTC Technical			
Ingredient Oxytetracycline Hydrochloride					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
71-1	Acute Avian Oral Toxicity - Quail & Duck	Cite All	See attached data submitters list	PAY	
71-2(a)	Acute Avian Dietary Toxicity - Quail	Cite All	See attached data submitters list	PAY	
71-2(b)	Acute Avian Dietary Toxicity - Duck	Cite All	See attached data submitters list	PAY	
71-4(a)	Avian Reproduction - Quail	Cite All	See attached data submitters list	PAY	
71-4(b)	Avian Reproduction - Duck	Cite All	See attached data submitters list	PAY	
72-1(a)	Freshwater Fish Toxicity (TGAI)	Cite All	See attached data submitters list	PAY	
72-1(b)	Freshwater Fish Toxicity (TEP)	Cite All	See attached data submitters list	PAY	
72-2(a)	Invertebrate Toxicity (TGAI)	Cite All	See attached data submitters list	PAY	
72-2(b)	Invertebrate Toxicity (TEP)	Cite All	See attached data submitters list	PAY	
Signature 			Name and Title Sharon M. Johnston President		Date January 16, 2003

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Date January 16, 2003		EPA Reg No./File Symbol 74896-		Page 4 of 9	
Applicant's/Registrant's Name & Address		RegGuide 509 Tower Valley Drive Hillsboro, MO 63050		Product RG OTC Technical	
Ingredient		Oxytetracycline Hydrochloride			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
81-1	Acute Oral Toxicity	Cite All	See attached data submitters list	PAY	
81-2	Acute Dermal Toxicity	Cite All	See attached data submitters list	PAY	
81-3	Acute Inhalation Toxicity	Cite All	See attached data submitters list	PAY	
81-4	Primary Eye Irritation	Cite All	See attached data submitters list	PAY	
81-5	Primary Dermal Irritation	Cite All	See attached data submitters list	PAY	
81-6	Dermal Sensitization	Cite All	See attached data submitters list	PAY	
81-8	Acute Mammalian Neurotoxicity	Cite All	See attached data submitters list	PAY	
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DATA MATRIX

Date January 16, 2003			EPA Reg No./File Symbol 74896-	Page 5 of 9	
Applicant's/Registrant's Name & Address RegGuide 509 Tower Valley Drive Hillsboro, MO 63050			Product RG OTC Technical		
Ingredient Oxytetracycline Hydrochloride					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
82-1(a)	90-Day Feeding Study – Rat	Cite All	See attached data submitters list	PAY	
82-1(b)	90-Day Feeding Study – Dog	Cite All	See attached data submitters list	PAY	
82-2	28-Day Dermal Toxicity – Rat	Cite All	See attached data submitters list	PAY	
82-4	28-Day Inhalation Toxicity – Rat	Cite All	See attached data submitters list	PAY	
83-1(b)	Chronic Feeding Study - Dog	Cite All	See attached data submitters list	PAY	
83-2	Oncogenicity Study - Mouse	Cite All	See attached data submitters list	PAY	
83-3(a)	Developmental Toxicity – Rat	Cite All	See attached data submitters list	PAY	
83-3(b)	Developmental Toxicity - Rabbit	Cite All	See attached data submitters list	PAY	
83-4	2-Generation Reproduction Study – Rat	Cite All	See attached data submitters list	PAY	
83-5	Combined Chronic Feeding/Oncogenicity Study – Rat	Cite All	See attached data submitters list	PAY	
Signature 			Name and Title Sharon M. Johnston President		Date January 16, 2003

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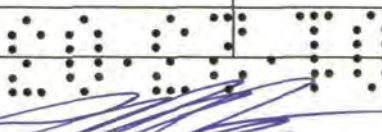


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Date January 16, 2003		EPA Reg No./File Symbol 74896-		Page 6 of 9	
Applicant's/Registrant's Name & Address RegGuide 509 Tower Valley Drive Hillsboro, MO 63050		Product RG OTC Technical			
Ingredient Oxytetracycline Hydrochloride					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
84-2	Gene Mutation (Ames Assay)	Cite All	See attached data submitters list	PAY	
84-2	Structural Chromosomal Aberration	Cite All	See attached data submitters list	PAY	
84-4	Other Genotoxic Effects	Cite All	See attached data submitters list	PAY	
85-1	General Metabolism - Rat	Cite All	See attached data submitters list	PAY	
85-3	Dermal Absorption	Cite All	See attached data submitters list	PAY	
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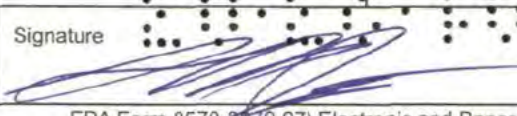


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Applicant's/Registrant's Name & Address RegGuide 509 Tower Valley Drive Hillsboro, MO 63050			Product RG OTC Technical		
Ingredient Oxytetracycline Hydrochloride					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
141-1	Honeybee Acute Contact LD50	Cite All	See attached data submitters list	PAY	
141-2	Honeybee Toxicity from Residue on Foliage	Cite All	See attached data submitters list	PAY	
Signature 			Name and Title Sharon M. Johnston President		Date January 16, 2003

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Applicant's/Registrant's Name & Address		RegGuide 509 Tower Valley Drive Hillsboro, MO 63050		Product RG OTC Technical	
Ingredient Oxytetracycline Hydrochloride					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
161-1	Hydrolysis	Cite All	See attached data submitters list	PAY	
161-2	Photodegradation - Water	Cite All	See attached data submitters list	PAY	
162-1	Aerobic Soil Metabolism	Cite All	See attached data submitters list	PAY	
162-2	Anaerobic Soil Metabolism	Cite All	See attached data submitters list	PAY	
163-1	Leaching & Adsorption/Desorption	Cite All	See attached data submitters list	PAY	
163-2	Lab Volatility	Cite All	See attached data submitters list	PAY	
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Applicant's/Registrant's Name & Address

RegGuide
509 Tower Valley Drive
Hillsboro, MO 63050

Product

RG OTC Technical

Ingredient

Oxytetracycline Hydrochloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
171-4(a)	Nature of the Residue – Plant Metabolism	Cite All	See attached data submitters list	PAY	
171-4(k)	Magnitude of the Residue – Crop Field Trials	Cite All	See attached data submitters list	PAY	
171-4(l)	Magnitude of the Residue – Processed Food	Cite All	See attached data submitters list	PAY	

Signature

Name and Title Sharon M. Johnston
President

Date
January 16, 2003

CHEMICAL CHEMICAL NAME

006308 Oxytetracycline hydrochloride

COMPANY# 001007 PFIZER INC

D/B/A PFIZER ANIMAL HEALTH, ATTN: JOHN B

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COMPANY# 066607 SPRAY DRIFT TASK FORCE

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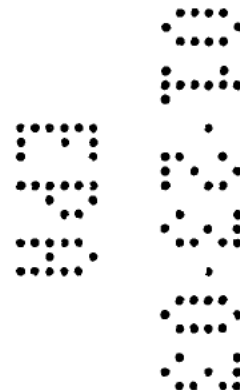
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